IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 06-230 (GMS)
	)	
APOTEX, INC.	)	**JURY TRIAL DEMANDED**
	)	
Defendant.	)	

APOTEX INC.'S MOTION FOR LEAVE TO FILE SURREPLY

Defendant Apotex, Inc. ("Defendant" or "Apotex") moves for leave to file the surreply attached hereto as Exhibit A. Recent developments in the Supreme Court, along with an argument made by Plaintiff Merck & Co., Inc. ("Plaintiff" or "Merck") for the first time in its reply brief, have occasioned this surreply.

First, Merck argued in its reply that the "collateral consequences" doctrine does not apply because the collateral injury to Apotex was not caused by Merck's lawsuit, but rather is a product of the statutory scheme under Hatch-Waxman. *See* Merck's Reply at p. 5. Merck is wrong because it filed suit and presented Apotex with a covenant not to sue, both of which actions resulted in direct harm to Apotex because of the thirty month stay. If Merck had not filed suit, Apotex's entry into the market would not be delayed by the thirty month stay. By presenting Apotex with a covenant not to sue, Merck avoids a court decision on the merits, which would have terminated the thirty month stay.

Second, Apotex retains a cognizable interest in this case because Merck's covenant does not protect Apotex's customers from patent infringement liability. This issue will shortly be before the Supreme Court because Pfizer Inc. ("Pfizer") presented Apotex with a covenant not to sue in *Apotex, Inc. v. Pfizer Inc.*, 385 F. Supp. 2d 187

(S.D.N.Y. 2005), *aff'd*, 159 Fed. Appx. 1013 (Fed. Cir. 2005), *petition for cert. filed*, 74 U.S.L.W. 3476 (U.S. Feb. 9, 2006) (No. 05-1006) in order to moot Apotex's petition for certiorari.[1] Pfizer's and Apotex's supplemental briefs are attached to Apotex's surreply. The Supreme Court has distributed Pfizer's suggestion of mootness for the conference of October 6, 2006. Because the *Apotex v. Pfizer* case could have a bearing on the present case, Apotex seeks to bring these recent developments in that case to the attention of this Court by way of the attached surreply.

CONCLUSION

For the foregoing reasons, Apotex respectfully requests that the Court grant leave for Apotex to file the surreply, attached hereto as Exhibit A.

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Dated: September 29, 2006
753223/20234

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[1] Pfizer also argued that the case was moot because the first generic applicant recently announced that it had begun making a generic version of the drug at issue in that case, thus triggering the 180-day exclusivity clock.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, Richard L. Horwitz, hereby certify that on September 29, 2006, the attached document was hand delivered on the following person and was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

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EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 06-230 (GMS)
	)	
APOTEX, INC.	)	**JURY TRIAL DEMANDED**
	)	
Defendant.	)	

APOTEX INC.'S SURREPLY TO
MERCK & CO., INC.'S REPLY BRIEF IN SUPPORT OF ITS
MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION

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INTRODUCTION

Recent developments in the Supreme Court, along with an argument made by Plaintiff Merck & Co., Inc. ("Plaintiff" or "Merck") for the first time in its reply brief, have occasioned this surreply by Defendant Apotex, Inc. ("Defendant" or "Apotex").

ARGUMENT

I. THE COLLATERAL CONSEQUENCES FACED BY APOTEX ARE A DIRECT RESULT OF MERCK'S ACTIONS

In its reply brief, Merck argues that the "collateral consequences" doctrine does not apply because the collateral injury to Apotex was not caused by Merck's lawsuit, but rather is a product of the statutory scheme under Hatch-Waxman. *See* Merck's Reply at p. 5 ("Apotex is in no different situation now, with Merck's covenant not to sue and a dismissal with prejudice, than it would have been in had Merck never sued Apotex at all for patent infringement."). Merck is wrong.

Merck has not sat on the sidelines as Pfizer did in *Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324 (Fed. Cir. 2005), *reh'g and reh'g en banc denied*, 405 F.3d 990 (Fed. Cir. 2005), *and cert. denied*, 126 S. Ct. 473 (2005). Instead, Merck has performed two acts which have directly caused the collateral injury that Apotex faces. First, Merck filed suit against Apotex. Merck's filing of suit within forty-five days of receipt of Apotex's paragraph IV certification results in a stay of Apotex's ANDA for thirty months. Second, Merck presented Apotex with a covenant not to sue in order to avoid an adverse decision on the merits that it knew was coming and that would have terminated the thirty month stay.[1]

[1] A court decision finding that Merck's patents were either invalid or not infringed would also trigger the first generic applicant's 180-day exclusivity period. The collateral injury

The statutory scheme set forth in the Hatch-Waxman Amendments (and as modified by the Medicare Amendments of 2003) provides that if Merck files an infringement action within forty-five days after receiving notice of the paragraph IV certification from Apotex, an automatic thirty-month "stay" goes into effect, during which the FDA cannot approve Apotex's ANDA unless the suit is resolved or the patent expires. *See Teva v. Pfizer*, 395 F.3d at 1328; 21 U.S.C. §355(j)(5)(B)(iii). More specifically, §355(j)(5)(B)(iii) provides that:

> If such an action is brought before the expiration of [45 days after the date on which the paragraph IV notice is received], **the approval shall be made effective upon the expiration of the thirty-month period** beginning on the date of the receipt of the notice...or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that...
>
> (I) **if before the expiration of such period the district court decided that the patent is invalid or not infringed** (including any substantive determination that there is no cause of action for patent infringement or invalidity), **the approval shall be made effective on**...
>
> (aa) **the date on which the court enters judgment** reflecting the decision; or
>
> (bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

21 U.S.C. §355(j)(5)(B)(iii) (2006) (emphasis added). Thus, the 30-month stay is only terminated by a court decision finding the patents that are subject to the paragraph IV certification invalid or not infringed.

In the present case, Apotex's paragraph IV certification was dated February 24, 2006. Merck filed its patent infringement suit on April 7, 2006, within 45 days of receiving notice of Apotex's paragraph IV certification. Thus, the automatic 30-month

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suffered by Apotex due to being delayed by the first generic applicant's 180-day exclusivity period was discussed in Apotex's response.

stay is in effect and the FDA cannot approve Apotex's ANDA for alendronate sodium until August 24, 2008, at the earliest. This is an additional 18 days after the 180-day exclusivity period would expire, assuming the first ANDA applicant enters the market on February 6, 2008, the date that Merck's patent on the active ingredient and the additional FDA exclusivity expires. Thus, Apotex suffers an injury in fact, *i.e.*, a 30-month delay of its ANDA approval, that is directly caused by Merck's filing of its lawsuit. Had Merck not sued Apotex within 45 days of receiving notice of Apotex's paragraph IV certification, approval of Apotex's ANDA would not be stayed for 30 months—a period of stay applicable only to Apotex that could prevent Apotex from entering the market beyond the expiration of the first generic applicant's 180-day exclusivity period, thus extending Merck's patent monopoly as to Apotex.

In incorporating the 30-month stay provision, the Hatch-Waxman Amendments were not designed so that brand name drug companies could file meritless suits, present covenants not to sue, and then dismiss the cases before there could be a decision on the merits with respect to validity or infringement in order to obtain a 30-month stay of the generic drug manufacturer's ANDA. However, that is precisely what Merck's strategy will bring about. It is a result not caused by the statutory scheme under the Hatch-Waxman Amendments, but by Merck's actions in filing its lawsuit against Apotex and attempting to dismiss the case because of its covenant not to sue instead of suffering a judgment on the merits.

The test under the collateral consequences doctrine is whether there is a specific, concrete injury caused by Merck that is redressable by a decision in Apotex's favor. *See*

Spencer v. Kemna, 523 U.S. 1, 7-9, 118 S. Ct. 978 (1998).[2] In the criminal context, such things as the deprivation of the right to vote, to hold office, to serve on a jury, or to engage in certain businesses, have long been presumed to be specific, concrete collateral consequences that attach to a wrongful conviction. *Id.* While there are obviously statutes, regulations, or rules that result in the disadvantages or disabilities that are the collateral consequences, it cannot be said that the disadvantages or disabilities are merely the product of those statutes or rules. The collateral consequences are also caused by the wrongful conviction.

In *Teva v. Pfizer*, the Federal Circuit did not find that the collateral consequences doctrine applied because there was no wrongful conduct by Pfizer. *See Teva v. Pfizer*, 395 F.3d at 1338 ("The injury about which Teva complains is the product of the Hatch-Waxman scheme *and the fact that Pfizer has acted in a manner permitted under that scheme*.") (emphasis added).[3] Pfizer merely listed its patents in the Orange Book as it was required to do. *Id.* at 1333. Pfizer did not sue Teva; nor did it attempt to dismiss the case based on a covenant not to sue Teva.

In the present case, there is wrongful conduct by Merck that, coupled with the Hatch-Waxman scheme, results in injury to Apotex. Merck filed its lawsuit against Apotex when it could have easily determined prior thereto whether Apotex infringed or not. It deliberately declined to request information from Apotex regarding Apotex's ANDA and filed suit. Then when it found out Apotex's ANDA would not infringe its

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[2] There is nothing in *Spencer* that limits the collateral consequences doctrine to criminal cases.

[3] Apotex disagrees with the Federal Circuit's holding of that case, and similar arguments before the Supreme Court in *Apotex v. Pfizer* are not yet decided.

patents, it presented Apotex with a covenant not to sue and sought to dismiss this case and Apotex's counterclaims for lack of subject matter jurisdiction.

This strategy inflicts two harms on Apotex. One, by filing suit, Apotex's ANDA is subject to a thirty month stay. Two, by avoiding a decision on the merits, the thirty month stay is not terminated earlier than thirty months and the first generic applicant's 180-day exclusivity is not triggered. Thus, Apotex could be kept out of the market until at least August 24, 2008, and possibly longer if the first ANDA applicant does not enter the market on February 6, 2008. If there is a court decision triggering event at least 180 days prior to February 6, 2008, the thirty month stay will be terminated and the 180-day exclusivity will be triggered so that Apotex can enter the market on February 6, 2008. Thus, Merck's filing of this lawsuit, and the covenant not to sue, have directly resulted in the harm to Apotex by delaying its entry into the market. These facts distinguish this case from *Teva v. Pfizer*, 395 F.3d at 1338.

II. MERCK'S COVENANT NOT TO SUE DOES NOT ELIMINATE THE CONTROVERSY BECAUSE IT DOES NOT PROTECT APOTEX'S CUSTOMERS

A further reason for this Court to maintain jurisdiction is that the covenant not to sue that Merck provided to Apotex in the present case does not apply to Apotex's suppliers and customers. *See* Merck's Motion at Ex. B. Since the covenant contains no admission that the patents are invalid or not infringed, Apotex's customers will still be at risk. They may opt to purchase the generic version from another company rather than assume the risk of patent infringement liability. Harm to customers may be considered in determining whether there is an actual controversy. *See Minnesota Mining and Mfg. Co. v. Norton Co.*, 929 F.2d 670, 673-74 and n. 4 (Fed. Cir. 1991) (district court erred in

failing to consider whether threats to 3M's customers caused harm to 3M); *Arrowhead Industrial Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 737 (Fed. Cir. 1988) (for test under declaratory judgment action, it was proper to consider whether customers may face an infringement suit or threat of one).

Whether harm to a declaratory judgment plaintiff's customers may be considered is currently before the Supreme Court. As Apotex mentioned in its response brief, Apotex filed a petition for certiorari in the case *Apotex, Inc. v. Pfizer Inc.*, 385 F. Supp. 2d 187 (S.D.N.Y. 2005), *aff'd*, 159 Fed. Appx. 1013 (Fed. Cir. 2005), *petition for cert. filed*, 74 U.S.L.W. 3476 (U.S. Feb. 9, 2006) (No. 05-1006). (*See* Apotex Response at p. 19.) At the time that Apotex filed its petition for certiorari, the facts in *Apotex, Inc. v. Pfizer Inc.* were similar to the facts in *Teva v. Pfizer*. In both cases, the brand name drug company (Pfizer) failed to file an infringement action against the generic drug company in response to the generic drug company's paragraph IV certification. The generic drug company then filed a declaratory judgment action in order to obtain a "court decision" triggering event. In both cases, the lawsuits were dismissed for lack of subject matter jurisdiction because there was no "reasonable apprehension" of patent litigation under the Federal Circuit's test for determining whether there is an "actual controversy" under the Declaratory Judgment Act, 28 U.S.C. §2201(a).

On September 1, 2006, Pfizer filed a supplemental brief in the Supreme Court informing the Court of recent developments that Pfizer argued rendered the case moot. *See* Supplemental Brief for Respondent, *Apotex Inc. v. Pfizer Inc.*, 159 Fed. Appx. 1013 (Fed. Cir. 2005) (No. 05-1006) (Ex. 1 hereto). More specifically, Pfizer asserted that it had sent Apotex a covenant not to sue Apotex with respect to the patent at issue since

Apotex filed its cert. petition, and also that Teva Pharmaceuticals Industries Ltd. ("Teva") had announced that it had begun marketing a generic version of Zoloft®, the drug at issue in that case, which started the 180-day exclusivity clock. *See* Supplemental Brief for Respondent at 1, *Apotex Inc. v. Pfizer Inc.* (No. 05-1006). Both events, Pfizer argued, rendered the case moot. *Id.*

On September 19, 2006, Apotex filed a supplemental brief arguing that the case was not moot notwithstanding the events Pfizer cited. *See* Supplemental Brief for Petitioners, *Apotex Inc. v. Pfizer Inc.*, 159 Fed. Appx. 1013 (Fed. Cir. 2005) (No. 05-1006) (Ex. 2 hereto). Apotex argued that it retained a cognizable interest in the outcome of the case because, among other things, the covenant does not apply to Apotex's suppliers and customers, without whom there is no market for Apotex's product. *See* Supplemental Brief for Petitioners at 1-2, *Apotex Inc. v. Pfizer Inc.* (No. 05-1006). On September 20, 2006, the Supreme Court distributed Pfizer's suggestion of mootness for the conference of October 6, 2006.[4]

The developments in the *Apotex v. Pfizer* case are potentially important to this case if the Supreme Court grants the cert. petition. The covenant not to sue provided by Pfizer in *Apotex v. Pfizer* brings the facts in that case closer to the facts in the case at bar. The difference in the present case is that Merck sued Apotex, whereas Pfizer did not. Moreover, if the Supreme Court finds the case is not moot for the reasons set forth by Apotex in its supplemental brief, this Court should find that the case at bar is not moot for similar reasons. If the Supreme Court decides the *Apotex v. Pfizer* case is moot, that

[4] This is two days after the oral argument in *MedImmune, Inc. v. Genentech, Inc.*, 427 F.3d 958 (Fed. Cir. 2005), *cert. granted*, 126 S. Ct. 1329, 74 U.S.L.W. 3457 (U.S. Feb. 21, 2006) (No. 05-608), which also involves the Federal Circuit's "reasonable apprehension" test, although under a different fact pattern.

would not necessarily render the present case moot since there is the added element in this case of the 30 month stay and there is the added element in *Apotex v. Pfizer* of the first generic having already entered the market.

In any event, the Court should wait until the Supreme Court decides whether to grant certiorari in *Apotex v. Pfizer*, as well as wait for the Supreme Court's decision in *MedImmune*, as rulings in both of those cases may have a significant impact on this Court's decision whether to dismiss this case.

CONCLUSION

For the foregoing reasons, Merck's motion to dismiss for lack of subject matter jurisdiction in light of Merck's covenant not to sue should be denied.

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Dated: September 29, 2006
753219/20234

Attorneys for Defendant Apotex, Inc.

EXHIBIT 1

No. 05- 1006

IN THE

Supreme Court of the United States

APOTEX INC. AND APOTEX CORP.,

Petitioners,

v.

PFIZER INC.,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

SUPPLEMENTAL BRIEF FOR RESPONDENT

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September 1, 2006

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of this Court's rules, respondent Pfizer Inc. ("Pfizer") states that it has no parent and no publicly held company owns 10% or more of its stock.

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SUPPLEMENTAL BRIEF FOR RESPONDENT

Pfizer submits this supplemental brief pursuant to Rule 16.8 of this Court's rules to inform the Court of factual developments occurring after Pfizer filed its opposition that have rendered the case moot.

STATEMENT OF THE CASE

Two intervening developments have eliminated any arguable present or future controversy between the parties about the patent that is the subject of this declaratory judgment action.

First, on August 10, 2006, Pfizer sent to counsel for Apotex an unconditional covenant not to sue Apotex with respect to that patent, United States Patent No. 5,248,699 (the "'699 patent"). *See* Addendum at 1a-2a. This covenant ensures that Apotex will never face any risk of a lawsuit by Pfizer under the subject patent.

Second, on August 14, 2006, Teva Pharmaceutical Industries Ltd. ("Teva"), the successor to Ivax Pharmaceuticals, Inc., publicly announced that it had begun marketing its generic version of Zoloft®. *See* Addendum at 3a-5a. Under the statutory regime applicable to this case (which has been amended for future cases, *see* Opp. at 3-5), Teva's marketing started the 180-day exclusivity period that Apotex sought to trigger with a hypothetical court judgment in its favor. *See* 21 U.S.C. § 355(j)(5)(B)(iv). Therefore, any future court judgment regarding the '699 patent would no longer have any effect on the exclusivity period.

Because of these developments, counsel for Pfizer suggested to Apotex that the case is moot and requested that Apotex withdraw its petition for a writ of certiorari. However, on August 18, 2006, counsel for Apotex replied that it did not consider the case moot and that it would not withdraw the petition. Apotex did not explain how any issue

in the case could survive the intervening developments described above.

SUPPLEMENTAL REASONS FOR DENYING THE PETITION

A case becomes moot if the plaintiff "no longer has a legally cognizable interest in the outcome." *City News & Novelty, Inc. v. City of Waukesha*, 531 U.S. 278, 283 (2001) (internal quotation marks omitted). Thus, where a complaining party has "received the full relief he requested," *Clayton v. Int'l Union, United Auto., Aero., & Agric. Implement Workers of Am.*, 451 U.S. 679, 692 (1981), there remains no constitutional case or controversy between the parties and the action becomes moot. In particular, a declaratory judgment action becomes moot when the relief requested by the plaintiff has become unnecessary because the underlying alleged injury has been removed or the relief sought from the court has already been provided. *See, e.g.*, *Golden v. Zwickler*, 394 U.S. 103, 109-10 (1969) (declaratory judgment action to adjudicate right to distribute literature opposing Congressman moot where Congressman became a judge); *Taylor v. McElroy*, 360 U.S. 709, 710-11 (1959) (per curiam) (action seeking declaratory and injunctive relief based on denial of security clearance mooted by issuance of clearance and guarantee against revocation based on subject grounds).

In this case, Apotex seeks to adjudicate whether a potential future generic drug contemplated by Apotex would infringe the '699 patent, and whether the '699 patent is valid. In light of Pfizer's covenant not to sue Apotex with respect to the '699 patent, Apotex no longer faces any risk of a lawsuit under that patent, thus eliminating any interest Apotex might have had in adjudicating either the patent's infringement or its validity. The covenant not to sue effectively gives Apotex the full relief that a court could provide in this action. Indeed, Apotex argued below that there was a cognizable dispute because Pfizer had *not* "given

Apotex a covenant not to sue." Brief for Plaintiffs-Appellants Apotex Inc. and Apotex Corp., No. 05-1199, at 19 (Fed. Cir. Mar. 22, 2005); *see also id.* at 41-42. Now that Apotex has received such a covenant, there is no potential present or future adversity between the parties about the '699 patent. The case is thus legally moot.

Apotex has argued that, apart from any threat of suit by Pfizer on the '699 patent, Apotex is harmed by its inability to use a hypothetical future court judgment in its favor to start the 180-day statutory exclusivity period in favor of Teva. As Pfizer explained in its opposition (at 21-24), this purported collateral "injury" could not properly sustain a declaratory judgment action against Pfizer regarding the '699 patent. But, in any event, any such issue is now also moot due to the intervening fact of Teva's marketing its generic product. Under the pre-amendments statutory regime applicable to this case, the exclusivity clock begins running with the earlier of Teva's marketing or a court judgment of non-infringement or invalidity. *See* 21 U.S.C. § 355(j)(5)(B)(iv). Now that Teva's marketing has already started the 180-day clock, no court judgment could have any effect on the exclusivity analysis, even if Apotex could obtain such a judgment before the 180-day period ended. Thus, even Apotex's non-justiciable interest in this case is legally moot.

Nor does this case fall within the exception to the mootness doctrine for issues that are capable of repetition yet evading review. That doctrine "applies only in exceptional situations." *City of Los Angeles v. Lyons*, 461 U.S. 95, 109 (1983). Specifically, in order for that narrow exception to apply, (1) the challenged action must be too short in duration "to be fully litigated prior to cessation or expiration," and (2) there must be a reasonable expectation that the same plaintiff will face the same issue again in the future. *Spencer v. Kemna*, 523 U.S. 1, 17 (1998). Neither of these requirements is even arguably satisfied here.

As to the durational requirement, this is not a case where there is some intrinsic reason why any future litigation over the same issue would be too short to allow judicial resolution of the issue, for example, because the underlying issue involves an inherently transitory condition, *see Roe v. Wade*, 410 U.S. 113 (1973), or because disputes of the kind at issue "typically are resolved quickly by executive or legislative action," *Burlington N. R.R. Co. v. B'hood of Maintenance of Way Employes*, 481 U.S. 429, 436 n.4 (1987). To the contrary, when Pfizer litigated the very same legal issue involving the same patent at issue here against another generic drug manufacturer, the case proceeded through final judgment, appeal, and Supreme Court review without the case becoming moot. *See Teva Pharms. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324 (Fed. Cir.), *reh'g denied*, 405 F.3d 990 (Fed. Cir.), *cert. denied*, 126 S. Ct. 473 (2005).

Nor is Apotex likely to face the same issue again in the future, *Spencer*, 523 U.S. at 17. In the first place, as shown in Pfizer's opposition (at 11-14), there is little likelihood that the patent issues to be adjudicated in this declaratory judgment action would recur, both because the statutory scheme has been fundamentally altered for future cases, and because the issues here are highly fact-bound. Moreover, given Pfizer's covenant not to sue, there is no chance of recurrence, because the issues in this case are whether an Apotex product would infringe the '699 patent, and whether that patent is valid. Now that Apotex has received an enforceable guarantee that it will never be sued on that patent, Apotex will assuredly never need to litigate those issues again in the future. *See, e.g., Deakins v. Monaghan*, 484 U.S. 193, 199-201 (1988) (respondent's commitment not to seek equitable relief precluded its reassertion and rendered the capable of repetition yet evading review exception unavailable). More generally, Apotex could not satisfy this prong of the "capable of repetition yet evading review" exception even with respect to the broader question of whether similar disputes involving different patents might

recur in the future. Patent rights are valuable and patentees do not lightly or frequently relinquish them. Thus, there is little reason to assume that Apotex will again face a situation where its desire to litigate validity and/or infringement issues will be mooted by issuance of a covenant not to sue, as innovators will not usually be willing to abandon valuable intellectual property rights.

As an illustration, in this case, the subject patent is not even the primary patent protecting Zoloft®; the subject patent merely claims one particular form of the active ingredient in Zoloft®. Thus, Pfizer was not willing to waive its rights on the '699 patent in the earlier *Teva* litigation, because the principal patent claiming that active ingredient was still viable and enforceable. However, once the basic patent expired, Ivax's ANDA was approved immediately, and the value of the '699 patent was transferred to Ivax by virtue of its license from Pfizer; after that, no lawsuit on the '699 patent could operate to maintain exclusivity for the Zoloft® brand. Once Teva's generic product entered the market, Pfizer lost any commercial interest in asserting the '699 patent. In short, Pfizer's decision to grant a covenant not to sue in this case is no basis for Apotex contending that it will be denied the opportunity in other cases to litigate validity and infringement issues.

In sum, the fact that Pfizer has given Apotex a covenant not to sue moots the case. Even a mere voluntary cessation of conduct can moot a case. *See, e.g.*, *County of Los Angeles v. Davis*, 440 U.S. 625, 631 (1979). While the potential for reinstitution of conduct voluntarily ceased sometimes keeps a case alive, an enforceable relinquishment of rights fully moots a dispute. *See, e.g.*, *Deakins*, 484 U.S. at 200-01. And, under this Court's cases, the mere "potential for manipulation" by repeating mootness-inducing conduct in future cases does not itself justify application of the exception. *Id.* at 200-01 & n.5 (potential reassertion in future case insufficient to avoid mootness). Indeed, the significant financial costs of forfeiting valuable patent rights

prevent any realistic possibility that covenants not to sue could be used as a systematic tool to manipulate the jurisdiction of the federal courts.

CONCLUSION

The petition for a writ of certiorari should be denied, or dismissed as moot.

Respectfully submitted,

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September 1, 2006

ADDENDUM

No. 05- 1006

IN THE

Supreme Court of the United States

APOTEX INC. AND APOTEX CORP.,

Petitioners,

v.

PFIZER INC.,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

COVENANT

WHEREAS, Pfizer Inc. ("Pfizer") owns all right, title and interest in and to United States Patent No. 5,248,699 ("the '699 patent"); and

WHEREAS Apotex Inc. and Apotex Corp. (together "Apotex") filed in the United States District Court for the Southern District of New York a civil action against Pfizer, Civil Action No. 04-CV-02539 (DC), in which Apotex sought a declaratory judgment that, inter alia, "the manufacture, sale, offer for sale, use, or importation of Apotex's proposed generic sertraline hydrochloride drug produce, that is the subject of ANDA No. 76-882, does not and will not infringe . . . any valid or enforceable claim of the '699 patent";

WHEREAS the civil action brought by Apotex was dismissed upon motion by Pfizer, and the dismissal of

Apotex's civil action was affirmed upon appeal to the United States Court of Appeals for the Federal Circuit;

WHEREAS Pfizer Inc., to avoid still further litigation with Apotex, will grant Apotex a covenant not to sue with respect to the '699 patent;

NOW THEREFORE, Pfizer hereby states as follows:

1. Pfizer unconditionally agrees, promises and covenants that Pfizer will not sue or otherwise enforce the '699 patent against Apotex in connection with the manufacture, sale, offer for sale, use, or importation of Apotex's proposed generic sertraline hydrochloride drug product, that is the subject of ANDA No. 76-882.

2. This covenant shall not be construed as a license, implied or otherwise, to any claim of any other patent, or any other claim or patent owned by or licensed to Pfizer, now or in the future. This covenant does not constitute an admission by Pfizer that the claims of the '699 patent are invalid or not infringed by Apotex in connection with the manufacture, sale, offer for sale, use, or importation of Apotex's proposed generic sertraline hydrochloride drug product, that is the subject of ANDA No. 76-882.

3. This covenant shall be binding upon and inure to the benefit of the parties and their respective successors-in-interest.

Dated: August 9, 2006 By: _____[signed]_____
Peter C. Richardson
Senior Vice President and
Associate General Counsel
Pfizer Inc.

Press Release

Teva Announces Launch of Generic Zoloft®

Jerusalem, Israel, August 14, 2006 — Teva Pharmaceutical Industries Ltd. (Nasdaq: TEVA) announced today that it has begun the sale of its generic version of Pfizer's Zoloft® (Sertraline) Tablets, 25 mg, 50 mg, and 100 mg in the United States. As the first company to file an ANDA containing a paragraph IV certification for this product, Teva has been awarded a 180-day period of marketing exclusivity.

Teva's AB-rated Sertraline Tablets are indicated for treatment of major depressive disorder. Annual brand product sales in the U.S. were approximately $3.1 billion for the twelve months ended June 2006, based on IMS data.

Teva Pharmaceutical Industries Ltd., headquartered in Israel, is among the top 20 pharmaceutical companies in the world and is the leading generic pharmaceutical company. The company develops, manufactures and markets generic and innovative human pharmaceuticals and active pharmaceutical ingredients, as well as animal health pharmaceutical products. Over 80% of Teva's sales are in North America and Europe.

Safe Harbor Statement under the U. S. Private Securities Litigation Reform Act of 1995: This release contains forward-looking statements, which express the current beliefs and expectations of management. Such statements are based on management's current beliefs and expectations and involve a number of known and unknown risks and uncertainties that could cause Teva's future results, performance or achievements to differ significantly from the results, performance or achievements expressed or implied by such forward-looking statements. Important factors that could cause or contribute to such differences include risks

relating to Teva's ability to rapidly integrate Ivax Corporation's operations and achieve expected synergies, Teva's ability to successfully develop and commercialize additional pharmaceutical products, the introduction of competing generic products, the impact of competition from brand-name companies that sell or license their own brand products under generic trade dress and at generic prices (so called "authorized generics") or seek to delay the introduction of generic product, the impact of consolidation of our distributors and customers, regulatory changes that may prevent Teva from exploiting exclusivity periods, potential liability for sales of generic products prior to a final resolution of outstanding litigation, including that relating to the generic versions of Allegra®, Neurontin®, Oxycontin® and Zithromax®, the effects of competition on Copaxone® sales, including as a result of the expected reintroduction of Tysabri® into the market, the impact of pharmaceutical industry regulation and pending legislation that could affect the pharmaceutical industry, the difficulty of predicting U.S. Food and Drug Administration, European Medicines Agency and other regulatory authority approvals, the regulatory environment and changes in the health policies and structures of various countries, Teva's ability to successfully identify, consummate and integrate acquisitions, potential exposure to product liability claims, dependence on patent and other protections for innovative products, significant operations worldwide that may be adversely affected by terrorism or major hostilities, environmental risks, fluctuations in currency, exchange and interest rates, operating results and other factors that are discussed in Teva's Annual Report on Form 20-F and its other filings with the U.S. Securities and Exchange Commission. Forward-looking statements speak only as of the date on which they are made and the Company undertakes no obligation to update publicly or revise any forward-looking statement, whether as a result of new information, future developments or otherwise.

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EXHIBIT 2

No. 05-1006

In the Supreme Court of the United States

APOTEX INC. AND APOTEX CORP.,

Petitioners,

v.

PFIZER INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

SUPPLEMENTAL BRIEF FOR PETITIONERS

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CORPORATE DISCLOSURE STATEMENT

The parent company of Apotex Inc. is Apotex Pharmaceutical Holdings, Inc. The parent company of Apotex Corp. is Apotex Holdings, Inc. There is no publicly-held corporation that owns 10% or more of either Apotex Inc. or Apotex Corp.

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SUPPLEMENTAL BRIEF FOR PETITIONERS

Apotex submits this supplemental brief, pursuant to Rule 15.8 of this Court's rules, in response to Pfizer's supplemental brief and suggestion of mootness.

STATEMENT OF THE CASE

The "factual developments" discussed in Pfizer's supplemental brief do not render this appeal moot or any less worthy of this Court's review. On the contrary, the underlying dispute between Apotex and Pfizer—regarding the improper application of the Federal Circuit's so-called "reasonable apprehension" test to the Hatch-Waxman declaratory judgment mechanism—remains very much a live controversy of critical importance to Apotex, the generic pharmaceutical industry, and the public that relies upon that industry to bring affordable medicines to market.

Apotex brought this declaratory judgment suit to alleviate the enormous harm that it was suffering, and continues to suffer, by virtue of Pfizer's conduct and refusal to resolve a legitimate patent dispute. Apotex's harm includes its inability to obtain approval of its non-infringing generic product and compete in the market *and* the debilitating uncertainty associated with potentially huge infringement damages. After two-plus years of litigation, Pfizer now seeks to moot this case with an unsolicited covenant not to sue. The Court should reject Pfizer's transparent attempt to manipulate this Court's jurisdiction and insulate the favorable decision below from review.

First, Apotex retains a cognizable interest in the outcome of this case notwithstanding Pfizer's strategically-timed covenant and Teva's generic product launch. The covenant does nothing to alleviate the harm caused by Apotex's inability obtain the approval needed to enter the market, as it is entitled to do. Nor does Pfizer's carefully-

worded covenant apply to Apotex's suppliers and customers, without whom there is no market for Apotex's product.

Second, even if Apotex's product is approved 180 days after Teva's launch, Pfizer's voluntary conduct does not moot this appeal because Pfizer cannot satisfy its formidable burden of showing that its conduct will not recur. This very same dispute already has occurred between Apotex and Pfizer with respect to the drug Accupril®. There, too, Pfizer attempted to manipulate the reviewing court's jurisdiction and insulate a favorable decision from review by providing Apotex with an unsolicited covenant on the eve of argument before the Federal Circuit. Moreover, this same dispute will occur again between Apotex and Pfizer regarding the drug Lipitor®. Thus, the underlying dispute here is not the rare, patent-specific event that Pfizer portrays it to be, but one that continues to plague Apotex and other generic companies.

Third, even if Pfizer's covenant and Teva's launch render this *particular* case moot, this dispute nonetheless falls squarely within the well-known "capable of repetition, yet evading review" exception to the mootness doctrine. The dispute already has occurred twice between Apotex and Pfizer, and undoubtedly will again. What's more, it will be too short in duration for meaningful review by this Court—Pfizer will see to that. The Court, therefore, should reject Pfizer's suggestion of mootness and grant the petition.

SUPPLEMENTAL REASONS FOR GRANTING THE PETITION

I. This Appeal Is Not Moot Because Apotex Retains A Legally Cognizable Interest In Its Outcome.

A case is moot "when the issues presented are no longer 'live' or the parties lack a legally cognizable interest in the outcome." *City of Erie v. Pap's A.M.*, 529 U.S. 277, 287 (2000). Neither is true here. The FDA continues to delay Apotex's approval based on an exclusivity period that

should have been triggered *years* ago. Pfizer's covenant does nothing to alleviate this enormous harm.

But even after Apotex's generic product is approved upon expiration of Teva's exclusivity, the threat and potential for infringement liability remains for Apotex's customers and suppliers. Pfizer's covenant applies only to Apotex, and does not constitute an admission that the patent is invalid or not infringed by Apotex's generic product. The covenant does not apply to Apotex's customers, who may opt instead to purchase the product from another company, rather than undertake the risk of patent infringement liability. Only a judgment of non-infringement or invalidity can alleviate this harm and risk. *See Minnesota Mining and Mfg. Co. v. Norton Co.*, 929 F.2d 670, 673-74 and n.4 (Fed. Cir. 1991) (noting that Declaratory Judgment Act sought to alleviate problems caused by threat of infringement liability to 3M and its customers, and rejecting argument that threats to 3M's customers did not cause harm to 3M). Thus, Apotex retains a legally cognizable interest in the outcome of this litigation even after its generic product is approved.

II. Pfizer Cannot, Through Voluntary Conduct, Manipulate This Court's Jurisdiction To Insulate A Favorable Decision From Review.

"A case might become moot if subsequent events made it absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs.*, 528 U.S. 167, 189 (2000); *accord United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953). But a "defendant's voluntary cessation of allegedly unlawful conduct ordinarily does not suffice to moot a case." *Friends of the Earth*, 528 U.S. at 174; *City of Mesquite v. Aladdin's Castle*, 455 U.S. 283, 289 (1983) (same). "If it did, the courts would be compelled to leave the defendant . . . free to return to his old ways." *Friends of the Earth*, 528 U.S. at 189. A "defendant claiming that its

voluntary compliance moots a case bears the formidable burden of showing that it is absolutely clear the allegedly wrongful behavior could not reasonably expected to recur." *Id.* at 190; *see also Adarand Constructors v. Slater*, 528 U.S. 216, 222 (2000) (same). Here, Pfizer cannot satisfy its formidable burden because its wrongful behavior will recur absent review by this Court. Indeed, this case is not the first time that this dispute has occurred between Apotex and Pfizer, nor will it be the last.

In 2003, Apotex filed a declaratory judgment action in an effort to obtain patent certainty and approval of its generic equivalent of Pfizer's Accupril® after Pfizer delayed filing suit in order to delay Apotex's approval. *See* Addendum at ¶ 5. A district court granted Pfizer's motion to dismiss the suit for lack of a case or controversy because Pfizer itself refused to file suit. *See TorPharm, Inc. v. Pfizer, Inc.*, No. Civ. 03-990, 2004 WL 1465756 (D. Del. June 28, 2004). On appeal, upon learning that the reviewing panel included two judges (Mayer, J. and Gajarsa, J.) who previously had expressed the view that a case or controversy exists in this circumstance, Pfizer precluded review by the Federal Circuit by sending Apotex an unsolicited covenant. *See* Addendum at ¶ 5. Pfizer did so only after it had delayed Apotex's approval for as long as it could without risking appellate review of a decision in its favor. *See id.*

Significantly, the very same dispute between Apotex and Pfizer will occur again with respect to Pfizer's Lipitor®. *See* Addendum at ¶¶ 6-12. Pfizer already has obtained a judgment of infringement on the basic patent against the first generic company to file a paragraph IV ANDA challenging all of the Orange Book-listed patents. *Id.* at ¶ 8. This means that the first-filer cannot go to market until the basic patent (and its pediatric exclusivity) expire on September 24, 2009. *Id.* But because Pfizer did not assert several later-expiring patents, the approval of all other generic applicants will be

delayed, both by the first-filer's exclusivity (see 21 U.S.C. § 355(j)(5)(B)(iv)), and the possibility of potentially catastrophic infringement damages on those patents. *Id.*

Apotex has developed its own generic Lipitor® and intends to submit an ANDA shortly. *See* Addendum at ¶ 9. Apotex intends to launch its generic product in September 2009, once the basic patent expires, provided that it can obtain patent certainty on the unasserted Pfizer patents. *Id.* Without court decisions on those patents, Apotex's approval, as well as the approval of any other generic applicants, will be delayed well beyond the expiration of the basic patent. *Id.* As with Accupril® and Zoloft®, however, Pfizer will have no incentive to, and likely will not, sue Apotex, precisely because Pfizer can delay generic competition longer and create a bottleneck by delaying suit and avoiding a court decision on the later-expiring patents. *Id.* at ¶¶ 10-11. As with Accupril® and Zoloft®, Apotex will have no choice but to file a declaratory judgment action against Pfizer in order to get prompt approval and patent certainty.

Thus, Pfizer cannot show that its conduct will not recur, let alone that it is "absolutely clear" that such conduct will not recur. As a result, Pfizer's suggestion that there "is little reason to assume" and no "realistic possibility" that Apotex will face this situation again where a brand company uses a covenant not to sue to manipulate the Court's jurisdiction is disingenuous, if not absurd.

In *Pap's*, after prevailing below in a challenge to a public indecency ordinance, Pap's attempted to moot the case and preclude review by this Court with an affidavit stating that it had ceased the allegedly offending conduct (*i.e.*, the operation of a nude dancing establishment). *See* 529 U.S. at 287. Pap's argued that the case therefore was moot because the outcome of the case "will have no effect upon Respondent." *Id.* This Court disagreed, holding that Pap's voluntary cessation did not moot the case. *See id.* The

Court also held that the city had an ongoing injury because it could not enforce its ordinance, and that the availability of relief allowing the city to do so was "sufficient to prevent the case from being moot." *Id.* at 288. The Court also acknowledged that *Pap's* did not present "a run of the mill voluntary cessation case" because it was the party "who, having prevailed below, now seeks to have the case declared moot." *Id.* The Court thus held that its "interest in preventing litigants from attempting to manipulate the court's jurisdiction to insulate a favorable decision from review further counsels against a finding of mootness here." *Id.*

Here, nothing prevents Pfizer from engaging in the same conduct with Apotex, or another generic company, that gave rise to this dispute. Indeed, Pfizer already has done so with respect to Accupril® and Zoloft®. Reversing the decision below would allow Apotex to bring a declaratory judgment claim to prevent such harm in the future. Moreover, it is Pfizer, who, "having prevailed below, now seeks to have the case declared moot." *Pap's*, 529 U.S. at 288. As in *Pap's*, this Court's interest in preventing such manipulation counsels against a finding of mootness. Nothing in the cases Pfizer cites suggests that a party that prevailed below can so blatantly manipulate the Court's jurisdiction to insulate a favorable decision from review.

III. Alternatively, This Case Falls Squarely Within The "Capable Of Repetition, Yet Evading Review" Exception To The Mootness Doctrine.

A case is not moot if the "underlying dispute between the two parties is one capable of repetition, yet evading review." *Gannett Co. v. DePasquale*, 443 U.S. 368, 377 (1979). This exception applies where "(1) the challenged action was in its duration too short to be fully litigated prior to its cessation or expiration, and (2) there was a reasonable

expectation that the same complaining party would be subjected to the same action again." *Id.*

First, the same underlying dispute—*i.e.*, application of the Federal Circuit's "reasonable apprehension" test to a declaratory judgment action filed by a generic company—is certainly capable of repetition. As set forth in Section II, *supra*, this same dispute happened before between the same parties in Accupril®, and in all likelihood, will happen again between these parties over Lipitor®. *See* Addendum at ¶ 6. The same dispute also will arise between Apotex and other brand companies on other products. *See id.* at ¶¶ 13-14.

Pfizer's argument that the underlying dispute can never happen again because it has vowed never to sue Apotex on *this particular patent* over *this drug* reads this Court's precedent far too narrowly. Indeed, if that were the law, the "capable of repetition, yet evading review" exception could *never* apply to any aspect of a patent dispute. But this Court has never narrowed its application in this manner. In fact, this Court explicitly has held that the same controversy can recur when different subject matter or different parties are involved.

For example, in a long line of cases relating to court orders restricting media access to criminal proceedings, this Court recognized that the complaining parties may be injured by other, future orders concerning different proceedings or issued by other courts. The Court repeatedly has held that such situations qualify as "capable of repetition." *See Nebraska Press Ass'n v. Stuart*, 427 U.S. 539, 546 (1976) ("[t]he dispute between the State and the petitioners who cover events throughout the State" is "capable of repetition" because state prosecutors are authorized to seek restrictive orders in appropriate cases); *Gannett*, 443 U.S. at 377-78 ("it is reasonably to be expected that the petitioner, as publisher of two New York newspapers, will be subjected to similar closure orders entered by New York courts"); *Globe*

Newspaper v. Superior Court, 457 U.S. 596, 603 (1982) (it could reasonably be assumed that newspaper publisher would someday be subjected to further orders excluding it from courtrooms during testimony in other sex-offense trials); *Richmond Newspapers, Inc. v. Virginia*, 448 U.S. 555, 563 (1980) (noting that "other trials may be closed by other judges," making appeal of order excluding public and press from courtroom "capable of repetition, yet evading review"); *Press-Enterprise Co. v. Superior Court of Ca* , 478 U.S. 1, 6 (1986) (controversy was "capable of repetition, yet evading review" because it could "reasonably be assumed that petitioner will be subjected to a similar closure order").

The Court also has held that the same controversy, despite having different underlying facts, can be "capable of repetition" in other analogous situations. For example, in *Securities and Exchange Comm'n v. Sloan*, the SEC said that it would no longer issue suspension orders against the respondent like the order at issue. *See* 436 U.S. 103, 108 (1978). The Court did not declare the dispute moot, finding a "reasonable expectation" that respondent would be subject to other orders suspending trading in the future, given the respondent's behavior and that the respondent owned other securities on which trading might also be suspended. *See id.* at 109-10. And in *Roe v. Wade*, the Court noted that "[p]regnancy often comes more than once to the same woman, and in the general population, if man is to survive, it will always be with us. Pregnancy provides a classic justification for a conclusion of nonmootness." 410 U.S. 113, 125 (1973).

Here, even if Pfizer (or another brand company) refuses to sue Apotex (or another generic company) on a different patent related to a different drug, the same controversy would repeat itself. Apotex has shown that the same controversy already has occurred between Apotex and Pfizer with respect to Accupril®, and will do so again for

Lipitor®. Pfizer's assertion that the issues are "highly fact-bound" (Pfizer Supp. Br. at 4) is belied by the repeated recurrence of this dispute between Apotex and Pfizer.[1] Thus, the controversy here undoubtedly is "capable of repetition."

Second, the challenged action always will be too short in duration for meaningful review because Pfizer always can give a covenant not to sue. Pfizer's own conduct allows the Court to disregard Pfizer's arguments to the contrary. Notwithstanding Pfizer's assertions about valuable patent rights and patentees not lightly or frequently relinquishing them (Pfizer Supp. Br. at 5), Pfizer itself has used covenants in two disputes involving Apotex in order to insulate a favorable decision from review. Every case involving this jurisdictional issue will be "short-lived" if the defendant is allowed to simply cease the controversy of its own accord after receiving a favorable appellate decision.[2]

Pfizer's conduct is analogous to the court orders in the SEC and court sealing cases, in which the orders expired before this Court could review the underlying issues. *See Sloan*, 436 U.S. at 109-10; *Nebraska Press Ass'n*, 427 U.S. at 546; *Gannett*, 443 U.S. at 377-78; *Globe Newspaper*, 457 U.S. at 603; *Richmond Newspapers*, 448 U.S. at 563; *Press-Enterprise*, 478 U.S. at 6. Here, Pfizer can argue that the case "expired," in effect, only because Pfizer decided it should, just as the courts and the SEC set limits on the lengths of their orders in those cases. And as in the voluntary cessation cases, this Court's "interest in preventing

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[1] Pfizer's assertion that the "statutory scheme has been fundamentally altered for future cases" is not true. *See* Pfizer Supp. Br. at 4. The ability of a generic company to obtain a declaratory judgment is, in fact, even more critical under the amended statute. *See* Apotex Reply Br. at 2-4.

[2] Pfizer's own argument that, if necessary, it could have mooted the *Teva* case at any time with a unilateral covenant not to sue destroys its reliance on the prior *Teva* litigation for the proposition that the dispute is not too short in duration. *See* Pfizer Supp. Br. at 5.

litigants from attempting to manipulate the Court's jurisdiction to insulate a favorable decision from review" should prevent Pfizer from unilaterally controlling the duration of the controversy in order to attempt to moot this case. *Pap's*, 529 U.S. at 288. This issue, largely through Pfizer's own conduct, has certainly evaded review, and will continue to do so as long as the defendants like Pfizer control the duration of the case.

CONCLUSION

The Court should reject Pfizer's suggestion of mootness and grant Apotex's petition for a writ of certiorari.

Respectfully submitted,

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September 19, 2006

No. 05-1006
IN THE

SUPREME COURT OF THE UNITED STATES

APOTEX INC. and APOTEX CORP.,

Petitioners,

v.

PFIZER INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

DECLARATION OF DR. BERNARD C. SHERMAN

I, DR. BERNARD C. SHERMAN, Ph.D., declare as follows:

1. I am the founder, Chairman and Chief Executive Officer of Apotex Inc. ("Apotex"), a Canadian-based pharmaceutical company that develops and manufactures quality generic medicines.

2. I have personal knowledge of the facts set forth herein, or believe them to be true based on my experience in the pharmaceutical industry and information I have received in the course of my duties, and am competent to testify to the same.

3. I submit this Declaration in response to Pfizer's supplemental brief and suggestion of mootness.

4. The underlying dispute between Apotex and Pfizer—regarding the Federal Circuit's application of its so-called reasonable apprehension test to the critical Hatch-Waxman declaratory judgment mechanism—already has occurred once between Apotex and Pfizer and I believe will recur again.

5. In 2003, Apotex filed a declaratory judgment action in an effort to obtain patent certainty and approval of its generic equivalent of Pfizer's Accupril®. A district court granted Pfizer's motion to dismiss the suit for lack of a case or controversy because Pfizer itself refused to file suit. On appeal, upon learning that the panel in the case included two judges (Mayer, J. and Gajarsa, J.) who had in previous cases expressed the view that a case or controversy exists in these circumstances, Pfizer attempted to preclude any meaningful review by the Federal Circuit by sending Apotex an unsolicited covenant not to sue—just as Pfizer has done in this case. Pfizer did so only after it had delayed Apotex's approval to the longest extent possible.

6. As with Pfizer's Accupril® in the prior case and Zoloft® here, the very same dispute between Apotex and Pfizer will occur again with respect to Pfizer's Lipitor®, the largest-selling prescription drug in the world today.

7. Pfizer has listed five (5) patents in FDA's Orange Book in connection with Lipitor®: U.S. Patent No. 4,681,893 ("the '893 patent"), expiring September 24, 2009 (with pediatric exclusivity to March 24, 2010); U.S. Patent No. 5,273,995 ("the '995 patent"), expiring December 28, 2010; U.S. Patent No. 5,686,104 ("the '104 patent"), expiring November 11, 2014; U.S. Patent No. 5,969,156

("the '156 patent"); and U.S. Patent No. 6,126,971 ("the '971 patent"), expiring January 19, 2013.

8. While the pertinent claim of the '995 patent has been held invalid, Pfizer already has obtained a judgment of infringement on the '893 patent against the first generic company to file a PIV ANDA challenging all of the Orange Book-listed patents. This means that the first-filer cannot go to market until the '893 patent (and its pediatric exclusivity) expire on September 24, 2009. But because Pfizer did not assert the later-expiring '104, '156 and '971 patents, the approval of subsequent generic ANDA applicants—even ones that have successfully designed around those patents—will be blocked and delayed, both by the first-filer's exclusivity, pursuant to 21 U.S.C. § 355(j)(5)(B)(iv), and the uncertainty associated with potentially catastrophic infringement damages on those patents.

9. Apotex has developed its own generic version of Lipitor® for which it intends to submit an ANDA shortly. Apotex intends to launch its generic product in September 2009 upon the expiration of the '893 patent, provided that Apotex can obtain patent certainty and court decisions on the unasserted Pfizer patents to clear the way for approval. Without court decisions on those patents, Apotex's approval, as well as the approval of any other generic applicants, will be delayed well beyond the expiration of the '893 patent.

10. As with Accupril® and Zoloft®, Pfizer will have no incentive to, and likely will not, sue Apotex, precisely because Pfizer can delay generic competition longer and create a bottleneck by delaying suit and avoiding any court decisions on the later-expiring '104, '156 and '971 patents.

11. In these circumstances, as with Accupril® and Zoloft®, Apotex will have no choice but to file another

declaratory judgment action against Pfizer in order to obtain approval of its product and patent certainty. This is the very same dispute that already occurred with respect to Accupril® and in the present case regarding Zoloft®. As before, Pfizer can attempt to manipulate the Court's jurisdiction yet again and preclude meaningful review by this Court by giving Apotex an unsolicited covenant not to sue.

12. The underlying dispute and circumstances of this case will continue to occur between Apotex and Pfizer as long as Pfizer is permitted to manipulate the Court's jurisdiction and insulate a favorable decision from review.

13. Furthermore, Apotex also has brought declaratory judgment claims against another brand company, Janssen, in connection with Apotex's attempt to market a generic version of Risperdal®. Janssen, like Pfizer, refused to bring suit against Apotex on the latest expiring listed patents. Once Apotex asserted its claims on these patents, Janssen moved to dismiss Apotex's declaratory judgment claims, citing, among other things, the Federal Circuit decision that Apotex asks this Court to review here.

14. Finally, Apotex has filed an ANDA for Trileptal®. Should Novartis Pharmaceuticals follow Pfizer's lead and attempt to delay approval of Apotex's ANDA by refusing to bring an infringement suit, Apotex will have no choice but to consider declaratory judgment claims in that situation as well.

15. The foregoing facts are true and correct as I verify and believe.

Dated this 14th day of September, 2006.

I, DR. BERNARD C. SHERMAN, hereby declare, under penalty of perjury under 28 U.S.C. § 1746 and the laws of the United States of America, that the foregoing Declaration is true and correct.

__/s/__Signature_____
DR. BERNARD C. SHERMAN

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